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DATE NOTICE SENT TO ALL PARTIES: 6/19/16

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
The item in dispute is the concurrent medical necessity of injection of Hydromorphone 20 mg/20mL, lower back.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
The reviewer is a Medical Doctor who is board certified in Anesthesia and Pain Management. The reviewer has been practicing for greater than 10 years.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the concurrent medical necessity of injection of Hydromorphone 20 mg/20mL, lower back.

PATIENT CLINICAL HISTORY [SUMMARY]:
Claimant is a female with a date of injury of XX/XX/XX. The mechanism of injury is a fall. Claimant was given diagnoses of chronic pain syndrome and low back pain. Patient was seen in clinic and presented with complaints of low back pain and post-laminectomy syndrome of the lumbar spine. She had 4/5 weakness in the left lower extremity in the extensors. She had 4/5 left lower extremity strength in the flexors. She had normal sensation in the lower extremities. It was noted that she had an intrathecal pain pump being managed elsewhere. The pump was interrogated and medication was ordered for a refill. Oxycodone was ordered for breakthrough pain and it was noted the patient had been on Dilaudid for a long period of time. The current request is for injection of hydromorphone 20mg/20ml, lower back.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Criteria used in analysis:
ODG Pain, Implantable drug-delivery systems (IDDSs)
First stage: Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration of 20mg/mL An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is 4mg/day with a concentration of 10mg/ML. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. (Wnara-Wolleat, 2006) (Deer, 2007) The previous 2003 Poly-analgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30mg/mL. They also recommended a maximum dose of hydromorphone of 10mg/day with a concentration of 30mg/mL (Hassenbusch, 2004) The newer maximum doses were recommended, in part, to prevent granulomas.

Second stage: If side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1mg/day and a concentration of 2mg/mL). Bupivicaine has also been recommended as an alternative to clonidine (maximum dose of 30mg/day and a concentration of 40mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent (Deer, 2007)

Third stage: The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. (Guillame, 2005) See also Ziconotide which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid)

Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription (Hassenbusch, 2004). According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17mL have been infused, and most

pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2-3 months. (Bennett, 2000)

This request is for an injection of Hydromorphone 20mg/mL to the lower back. The records indicate the patient has an intrathecal pain pump but does not indicate what medications have been placed in that pain pump. Pain scores have not been objectively identified. The specific request is for an injection and does not indicate whether this is for the pain pump or for a local injection of Hydromorphone. Lacking efficacy of the pain pump and lacking clarification, this request is not supported and is non-certified.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**